REMARKS

Specification

The specification has been amended as requested by the Examiner.

Rejection of the claims under 35 USC 103:

Claims 5 and 7 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman et al (US Patent 6,835,393) in view of Oda et al. (Journal of the National Cancer Institute, Vol. 79, No. 6, p. 1205-1211, 1987). Applicants have amended the claims to obviate the rejection. Specifically, Applicants have amended the claims to recite "reacting the anhydride monomers in the copolymer with hydrophobic amines or hydrophobic alcohols". Support for the amendment can be found in the specification on page 4 lines 24-25, page 5 lines 3-4, Examples 3 (an excess of hydrophobic alcohol is reacted with the anhydride monomers), Examples 4 (1 equivalent of hydrophobic amine is reacted with the anhydride monomers), Example 5 (SMA polymer reacted with an excess of hydrophobic alcohol or hydrophobic amine). Applicants have further amended the claims to recite forming a styrene-maleic anhydride random copolymer having 50% styrene and 50% maleic anhydride. Support for the amendment can be found in the specification as originally filed on page 13 lines 29-31.

Hoffman et al. teach at column 6 lines 42-52: "Any polymer can be used which is not hydrophobic at physiological pH, typically in the range of between 6.8 and 7.5, and approximately 7.4 inside cells, but which becomes hydrophobic at the pH inside the endosomes (between 5.0 and 6.5). Polymers which include multiple carboxylic acid groups, for example, polymers with more than 0.5 carboxylic acid groups per monomer on average, tend to be relatively hydrophilic at pH ranges in which the carboxylic acid groups are deprotonated, and tend to be relatively hydrophobic at pH ranges in which the carboxylic acid groups are protonated."

One skilled in the art would understand that Hoffman et al. teaches that the polymer must have at least 1 carboxyl monomer group for each hydrophobic monomer group for the polymer to have the desired characteristics, a balance of charge and hydrophobicity. Applicants' polymers have less than 1 carboxyl monomer group per hydrophobic monomer group.

Oda et al. teaches polymers having 30-45% maleic anhydride groups (i.e. 55-70 styrene groups per 45-30 anhydride groups.) Oda et al. further teaches half-esterification of 50-70% of the maleic anhydride groups.

Applicants claim a polymer containing 50% styrene groups to 50% maleic anhydride groups. Applicants further claim half-esterification (modification) of all the anhydride groups, "reacting the anhydride monomers…".

Neither Oda et al. nor Applicants teach or claim polymers having equimolar numbers of carboxyl groups and hydrophobic groups as taught by Hoffman et al. Further, neither Hoffman et al. nor Oda et al. teach Applicants' claimed polymers. Oda et al. teach polymers having 85-96.5 hydrophobic groups to 15-31.5 carboxyl groups to 9-22.5 anhydryde groups. In contrast, Applicants claim polymers having 100 hydrophobic groups to 50 carboxyl groups. [Half-esterification of a single anhydride yields one hydrophobic group and one carboxylic acid group; e.g., 50% half esterification of 30 anhydride groups with butyl-amine yields 15 butyl groups, 15 carboxyl groups (together half of the anhydride) and 15 anhydride groups.]

Claims 12 and 16 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman et al (US Patent 6,835,393) in view of Saettone et al. ("Inserts for Sustained Ocular Delivery of Pilocarpine: Evaluation of a Series of Partial Esters of (Maleic - Alkyl Vinyl Ether) Alternating Copolymers." Polymers in Medicine III: Third International Conference on Polymers in Medicine, Porto Cervo Italy, Ed. Migliarese, C., et al. Elsevier Science Publishers B. V., p. 209-224, 1998). As argued above, Hoffman et al. teaches away from the polymers taught by Seattone et al. or claimed by the Applicants. Neither Seattone et al. nor Applicants teach or claim polymers having equimolar numbers of carboxyl groups and hydrophobic groups as taught by Hoffman et al.

It is well accepted that an invention is usually a combination of previously known things. Patent law also clearly supports that new uses for old products is patentable subject matter. Applicants acknowledge they did not invent a polymer having carboxyl groups and hydrophobic groups as taught by Hoffman et al. Applicants further acknowledge that they did not invent polymers made by polymerization of alkyl vinyl ether-maleic anhydride alternating copolymer nor their esterification to add hydrophobic groups (Saettone et al.)

It is the Applicants' opinion that the disclosure of Hoffman et al. can not be reasonably considered to render as obvious for nucleic acid delivery any and all polymers having both carboxyl groups and hydrophobic groups. There exists a limitless number of such polymers known in the art having an enormous range of physical, chemical and biologically characteristics. It is further the Applicants' opinion that it is not reasonable to conclude that all polymers having carboxyl groups and hydrophobic groups will possess similar properties and their vast number precludes any particular one being obvious for any specific purpose without further suggestion or motivation beyond having these two monomers or groups.

Thus, if the disclosure of Hoffman et al. does not render all such polymers obvious, it can not be considered obvious to try the particular polymers taught by Scattone et al. absent some suggestion or motivation. Scattone et al. teach the use alkyl vinyl ether-maleic anhydride alternating copolymer as matrices for the fabrication of inserts containing pilocarpine for sustained release matrices in ocular delivery. Scattone et al. teach the use of the matrices to slowly *release* (sustained release) the pilocarpine from the polymer. Scattone et al. do not teach the polymers have membrane activity or are endocytosed and teach away from the polymer being endocytosed together with the biologically active compound (pilocarpine).

In view of the amendments and arguments, Applicants request reconsideration of the rejection.

The Examiner's objections and rejections are now believed to be overcome by this response to the Office Action. The Action states that claims 5, 7, 12, and 16 are allowed. Applications have canceled the rejected claims.

Respectfully submitted,

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I hereby certify that this correspondence is being transmitted to the USPTO on this date: 23 June 2010 .

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